

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Donohoe, Brendan M.; et. al.

Assignee: Cardica, Inc.

Title: Method and Apparatus for Creating an Opening in the Wall of a Tubular Vessel

Serial No.: 10/054,745 Filing Date: January 22, 2002

Examiner: Vy Q. Bui Group Art Unit: 3731

Docket No.: 057

March 23, 2007

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P. O. Box 1450
Alexandria, VA 22313-1450

REPLY BRIEF UNDER 37 CFR §41.41 AND MPEP 1208(I)

This Reply Brief is prepared and submitted in response to the Examiner's Answer mailed on February 5, 2007.

I. STATUS OF CLAIMS

Claims 1-15, 17-31, 33-39 and 51 stand finally rejected. Claims 32 and 40-50 have been objected to. These claims are set forth in the appendix attached hereto.

Claims 16 and 52-61 have been withdrawn. These claims are not at issue and are not set forth in the appendix attached hereto.

II. GROUNDs OF REJECTION TO BE REVIEWED ON APPEAL

A. Claims 1-15

Independent claim 1 stands finally rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 3,825,362 to Hougen (“Hougen”). Dependent claims 5-6 and 8-14 also stand rejected under Hougen. Independent claim 1 also stands finally rejected under 35 U.S.C. §102(b) as being anticipated by the St. Jude Medical Instructions for Use.” Dependent claims 7 and 15 also stand finally rejected under that reference.

B. Claims 17-31, 33-39 and 51

Independent claim 17 and dependent claims 18-31, 33-39 and 51 stand finally rejected under 35 U.S.C. §102(b) as being anticipated by Hougen.

III. ARGUMENTS

A. Claims 1-15

As claimed in claim 1, both the piercing member and the cutter “translate together to penetrate the wall of the vessel.” As set forth in the specification, the phrase “translate together” means that the piercing member and the cutter are “fixed...with respect to translation” to penetrate the wall of the vessel.¹

U.S. Pat. No. 3,825,362 to Hougen (“Hougen”) describes a pointed pilot pin 42 coaxial with an annular hole cutter 14.² The Office Action analogizes the pilot pin 42 of Hougen to the claimed piercing member, and analogizes the cutter 14 of Hougen to the claimed cutter.³ As the tool of Hougen is actuated, the “pilot pin 42 progressively retracts as cutter 14 advances into the workpiece.”⁴ That is, the pilot pin 42 and the cutter 14 of Hougen do not “translate together to penetrate the wall of the vessel” as required by claim 1, but instead translate in opposite directions to cut a hole in the workpiece. To interpret the phrase “translate together” to include “translation in opposite directions” would vitiate the claim limitation “together” in violation of the MPEP, which requires that “all words in a claim must be considered in judging the patentability of that claim against the prior art.”⁵

Further, claim 1 requires that the piercing member and the cutter “translate together to penetrate the wall of the vessel.” The Answer points to Figure 2 of Hougen in support of the rejection of claim 1, and states that “during a translation movement of Hougen device before contacting wall 12, cutter 12 [sic] and auger/spike/piercing member 42 are axially fixed to one another because there is substantially no relative motion between cutter 14 and

¹ *Id.*; page 3, lines 21-22.

² Hougen; *e.g.*, col. 2, lines 36-37, 59-62; Figures 2-4, 6-15.

³ Final Action, page 2.

⁴ Hougen; col. 4, lines 1-2; *e.g.*, Figures 2-3, 12-14. (emphasis added).

auger/spike/piercing member 42.”⁶ Figure 2 of Hougen shows the tool of Hougen spaced apart from the workpiece 12, before contacting and cutting the workpiece 12. However, any relative motion, or lack thereof, of components of the tool of Hougen before penetration of a workpiece is irrelevant to claim 1, which requires that the piercing member and the cutter “translate together to penetrate the wall of the vessel.”

Next, at no time during prosecution of this application has the Patent Office contended that the St. Jude Medical Instructions for Use disclose the claimed piercing member and cutter that “translate together to penetrate the wall of the vessel.” The Final Action of May 18, 2006 states in regard to that reference, *in toto*, that “Figs. 14 and 15 of ‘St. Jude Medical, Instruction for Use’ shows a device as recited in the claims including a cutter beveled outward and a needle/barb/spike having a width at the proximal end greater than the width of the needle shaft.” Turning to the Answer, it simply states in regard to that reference, *in toto*, that “[a]s to the reference of ‘St. Jude Medical Instruction for Use,’ a similar rationale is applicable to the Applicants’ arguments.” Neither of these rejections contend or even suggest that the St. Jude Medical Instructions for Use describe a piercing member and cutter that “translate together to penetrate the wall of the vessel.” Based on this record alone, claim 1 should be allowed over the St. Jude Medical Instructions for Use.

The St. Jude Medical Instructions for Use discloses a needle positioned within a cutter blade, where that needle is movable in translation relative to the cutter blade.⁷ The user is directed to “[r]otate the cutter blade to advance through the aorta until the hole is complete.”⁸

⁵ MPEP 2143.03 (quoting *In re Wilson*, 424 F.2d 1382, 1385 (CCPA 1974)).

⁶ Examiner’s Answer; page 6. (emphasis added).

⁷ St. Jude Medical Instructions for Use; page 7; Figures 13-15.

⁸ *Id.*, page 7; Figure 15.

The cutter blade advances while the needle is substantially stationary.⁹ Thus, the needle and cutter blade translate relative to one another to penetrate the wall of the target vessel, and therefore do not “translate together to penetrate the wall of the vessel.”

Thus, neither Hougen nor the St. Jude Medical Instructions for Use expressly or inherently describes each and every element claimed in claim 1, as required for anticipation under MPEP 2131, and as a result claim 1 is believed to be in condition for allowance. Claim 1 was acknowledged as generic in the Office Action of August 24, 2005, so allowance of generic claim 1 would be as to all species. Claims 2-15 depend from claim 1, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

With regard to dependent claim 10, the Examiner’s Answer states a conclusion, with no citation to the drawings or specification of Hougen and no analysis, that “the cutter can be considered as a cap or plug being substantially hemostatic.”¹⁰ This statement is an improper inherency rejection, because it is unsupported contrary to the requirements of the MPEP: “In relying upon the theory of inherency, the examiner must provide a basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art.”¹¹ The device of Hougen is a “machine tool”¹², and the Answer provides no analysis of how using a machine tool to cut tissue would result in anything other than an industrial accident, much less any analysis of how the jagged-edged cutter 14 of that machine tool could be “substantially hemostatic.”

⁹ *Id.*

¹⁰ Examiner’s Answer, page 7.

¹¹ MPEP 2112 (*citing Ex parte Levy*, 17 U.S.P.Q.2d 1461, 1464 (Bd. Pat. App. & Inter. 1990)) (emphasis in original).

¹² Hougen; col. 1, lines 63-65; col. 2, lines 50-51.

B. Claims 17-31, 33-39 and 51

Claim 17 is directed to a surgical tool for removing tissue from the wall of a vessel to create an opening, where that tool comprises, among other elements, “a rotatable cutter [and] an auger assembly fixed to and substantially coaxial with said cutter.” The auger assembly includes an auger at its distal end. Because the claimed auger assembly is “fixed to” the cutter, it is necessarily fixed to the cutter in translation and rotation: “Because the auger and the cutter are fixed to one another, they rotate and advance together to penetrate the wall of a tubular vessel and cut tissue from it.”¹³

The standard usage of the term “fixed” is “firmly placed or attached, not movable.”¹⁴ As set forth above, the pilot pin 42 and the cutter 14 of Hougen move in opposite translational directions to cut a hole in the workpiece, such that the pilot pin 42 is movable relative to the cutter 14. Thus, the pilot pin 42 and the cutter 14 are not and cannot be fixed to one another. The Answer contends that the cutter 14 and pilot pin 42 are “axially fixed to each other because there is substantially no relative motion” between them.¹⁵ However, the lack of relative motion at a particular time between the cutter 14 and pilot pin 42 does not imply that the two are “not movable”, and therefore fixed, relative to one another. Indeed, Hougen moves the cutter 14 and the pilot pin 42 in opposite directions to cut a hole in the workpiece – a feat Hougen could only accomplish if the cutter 14 and the pilot pin 42 were not fixed (*i.e.*, were movable) relative to each other.

None of the references expressly or inherently describes each and every element claimed in claim 17, and as a result claim 17 is believed to be in condition for allowance.

¹³ Specification; page 3, lines 14-16.

¹⁴ WEBSTER’S NEW WORLD DICTIONARY, SECOND COLLEGE EDITION 528 (1978).

¹⁵ Examiner’s Answer, page 6.

Claims 18-31, 33-39 and 51 depend from claim 17, and are thus believed to be in condition for allowance as well under MPEP 608.01(n)(III).

With regard to dependent claim 38, that Hougen does not describe “an impulse source configured to rotate and translate said auger and said cutter.” The terms “impulse” and “impulse source” are expressly defined in the Specification, under MPEP 2111.01(IV):

A force that acts on a body for a short time but produces a large change in its linear or angular momentum is called an impulsive force. As used in this document, the term “impulse source” refers to a source of such an impulsive force.¹⁶

That is, the claimed “impulse source” is the source of a force that acts on a body for a short time but produces a large change in its linear or angular momentum. Turning to claim 38, that “body” is “said auger and said cutter.” The Answer states that “spindle 40 of a machine such as a press drill [provides] impulse source.”¹⁷ However, Hougen merely states that a spindle 40 is a rotary driven member,¹⁸ and describes nothing about the claimed “impulse source”; that is, nothing about a source of a force that acts on the auger and cutter for a short time but produces a large change in their linear or angular momentum.

¹⁶ Specification; page 15, lines 22-25.

¹⁷ Examiner’s Answer, page 7.

¹⁸ Hougen; col. 2, lines 55-59.

VII. CONCLUSION

For the above reasons, Applicants respectfully submit that the rejection of pending claims 1-15, 17-31, 33-39 and 51 was unfounded. Accordingly, Applicants request that the rejection of those claims be reversed and that those claims be allowed.

Respectfully submitted,

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EVIDENCE APPENDIX

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akin? to ON. *fita*, to knit, tie ends of thread, akin to OHG. *fizza*, skein of thread, ult. < IE. **pedyo-*, of the foot < base **ped-*, FOOT] 1. to be suitable or adapted to; be in accord with [let the punishment fit the crime] 2. to be the proper size, shape, etc. for 3. a) to make or alter so as to fit b) to measure (a person) for something that must be fitted / fit him for a brace] 4. to make suitable or qualified [his training fits him for the job] 5. a) to insert, as into a receptacle / to fit a key in a lock/ b) to make a place for (with in or into) / to fit another passenger into the crowded car] 6. to equip; outfit (often with out) —vi. 1. to be suitable or proper 2. to be suitably adapted; be in accord or harmony (often with in or into) 3. to have the proper size or shape for a particular figure, space, etc. / his coat fits well, this won't fit into the box/ —adj. fit'ter, fit'test [ME. *fyt*] 1. adapted, adjusted, qualified, or suited to some purpose, function, situation, etc. / food fit to eat/ 2. proper; right; appropriate 3. in good physical condition; healthy 4. [Colloq.] disturbed enough; inclined /she was fit to scream/ —n. [prob. < the v.] 1. the condition of fitting or being fitted 2. the manner or degree of fitting or of fitting together /a good fit, a tight fit/ 3. anything that fits —fit to be tied [Colloq.] frustrated and angry **SYN.** —fit, the broadest term here, means having the qualities or qualifications to meet some condition, circumstance, purpose, or demand / fit for a king/; suitable is applied to that which accords with the requirements or needs of the occasion or circumstances /shoes suitable for hiking/; proper implies reference to that which naturally or rightfully belongs to something or suggests a fitness or suitability dictated by good judgment / proper respect for one's elders/; that is appropriate which is especially or distinctively fit or suitable; fitting is applied to that which accords harmoniously with the character, spirit, or tone of something; apt, in this connection, is used of that which is exactly suited to the purpose [an apt phrase]

fit² (fit) n. [ME. < OE. (rare) *fitt*, conflict] 1. any sudden, uncontrollable attack; paroxysm /a fit of coughing/ 2. a) a sharp, brief display of feeling /a fit of anger/ b) a transient mood /a fit of the blues/ 3. a temporary burst of activity 4. **Med.** a seizure in which the victim loses consciousness or has convulsions or both —by fits (and starts) in an irregular way; in bursts of activity followed by periods of inactivity —have (or *throw) a fit [Colloq.] to become very angry or upset

fit³ (fit) n. [ME. *fitt* < OE. *fitt*, akin to OS. (Latinized) pl. *vittas*, sections of a poem (the *Heland*), OHG. *fizza*; see FIT¹] [Archaic] a short section of a poem, ballad, or song

fitch (fich) n. [ME. *ficheu* < OFr. *fichau* < MDu. *witsche*, akin to OHG. *wiesse*, WEASEL] 1. same as POLECAT (sense 1) 2. its pelt or fur Also **fitch'et** (-it), **fitch'ew** (-oo)

Fitch (fich) 1. (William) Clyde, 1865-1909; U.S. playwright 2. John, 1743-98; U.S. inventor of a steamboat

Fitch-burg (fich'burg) [after John Fitch, local civic leader] city in N Mass.: pop. 43,000

fit-ful (fit'fəl) adj. [FIT² + -FUL] characterized by irregular or intermittent activity, impulses, etc.; spasmotic; restless —fit'ful·ly adv. —fit'ful·ness n.

fit-ly (fit'lē) adv. 1. in a fit manner; suitably 2. at the right time

fit-men't (-mənt) n. [Chiefly Brit.] any of various furnishings, fixtures, or detachable parts

fit-ness (-nis) n. the condition of being fit; suitability, appropriateness, healthiness, etc.

fit-ted (fit'it) adj. designed to conform to the contours of that which it covers /fitted bed sheets, a fitted coat/

fit-ter (-er) n. a person who fits; specif., a) a person who alters or adjusts garments to fit b) a person who supplies, installs, or adjusts machinery, pipes, etc.

fit-ting (-in) adj. suitable; proper; appropriate —n. 1. an adjustment or trying on of clothes, etc. for fit 2. a small part used to join, adjust, or adapt other parts, as in a system of pipes 3. [pl.] the fixtures, furnishings, or decorations of a house, office, automobile, etc. —SYN. see FIT¹ —fit'ting-ly adv.

Fitz-Ger-al'd (fits jer'ald), Edward (born Edward Purcell) 1809-83; Eng. poet & translator of *The Rubáiyát*; also written Fitzgerald

Fitz-ge-rald (-jer'ald), F(rancis) Scott (Key) 1896-1940; U.S. author

Fiu-me (fyoo'me) former (It.) name of RIJEKA

five (fiv) adj. [ME. < OE. *fif*, with assimilated nasal, akin to G. *fünf* (OHG., Goth. *fimf*) < IE. base **penkwe*, whence Sans. *páñca*, Gr. *pente*, L. *quincus*] totaling one more than four —n. 1. the cardinal number between four and six; 5; V 2. any group of five people or things, esp. *as* a basketball team 3. something numbered five or having five units, as a) a playing card, domino, face of a die, etc. etc. b) [Colloq.] a five-dollar bill

five-and-ten-cent store (-'n ten'sent) a store that sells wide variety of inexpensive merchandise, orig. with many articles priced at five or ten cents: also **five-and-ten**, **five-and-dime** ('n dim') n.

Five Civilized Tribes the Cherokee, Chickasaw, Choctaw, Creek, and Seminole tribes of the Indian Territory (now the eastern part of Oklahoma)

five-fin-ger (fin'gar) n. [OE. *fifingre*] 1. same as CINQUEFOIL (sense 1) 2. same as VIRGINIA CREEPER 3. any of various plants having leaves with five parts or flowers with five petals

five-fold (-fold') adj. [see -FOLD] 1. having five parts 2. having five times as much or as many —adv. five times as much or as many

five hundred a variety of euchre or rummy in which the object is to score five hundred points

Five Nations a confederation of Iroquoian Indians, including the Mohawks, Oneidas, Onondagas, Cayugas, and Senecas; see also SIX NATIONS

five'er (fi'ver) n. [Slang] 1. a five-dollar bill 2. [Brit.] a five-pound note

fives (fivz) n. [*as* ? five fingers of the hand] a kind of hand-ball played in England

fix (fiks) vt. fixed, fix'ing [ME. *fixen* < L. *fixus*, pp. of *figere* to fasten, attach: for IE. base see FINISH] 1. a) to make firm, stable, or secure b) to fasten or attach firmly 2. to set firmly in the mind 3. a) to direct steadily /to fix the eyes on a target/ b) to direct one's eyes steadily at /to fix the target/ 4. to make rigid or stiff /to fix one's jaw/ 5. to make permanent or lasting /color is fixed in dyeing/ 6. to arrange or establish definitely; set /to fix the date of a wedding/ 7. to arrange properly or in a certain way; set in order; adjust 8. to restore to proper condition; repair, mend, remedy, heal, etc. 9. to, bank, refuel, and tend (a fire) 10. to prepare and cook (food or meals) 11. to preserve (a specimen) so that its tissue, etc. can be used for microscopic study 12. [Colloq.] to influence the result or action of (a horse race, jury, election, etc.) to one's advantage by bribery, trickery, etc. 13. [Colloq.] to revenge oneself on; get even with; punish or chastise 14. [Colloq.] to spay or castrate 15. **Chem.** a) to make solid or nonvolatile b) to cause (atmospheric nitrogen) to combine with other elements or compounds to form nitrates, ammonia, etc. 16. **Photog.** to make (a film, print, etc.) permanent and prevent from fading by washing in a chemical solution —vi. 1. to become fixed, firm, or stable 2. [Colloq. or Dial.] to prepare or intend /I'm fixing to go hunting/ —n. 1. the position of a ship or aircraft determined from the bearings of two or more known points or from radio signals 2. [Colloq.] a difficult or awkward situation; predicament 3. [Slang] a) the act of fixing the outcome of a contest, situation, etc. b) a contest, situation, etc. that has been fixed 4. [Slang] an injection of a narcotic, as heroin, by an addict —SYN. see PREDICAMENT

fix on (or **upon**) to choose; settle on —fix up [Colloq.] 1. to repair, mend, remedy, etc. 2. to arrange properly; set in order 3. to make arrangements for —fix'a-ble adj.

fix-ate (fik'sat) vt., vi. -at-ed, -at-ing [*as* ML. *fixatus*, pp. of *fixare*: see FIX] to make or become fixed; specif., 1. to direct and focus (the eyes) on (a point or object) 2. **Psychoanalysis** to attach or arrest (the expression of the libidinal or aggressive drive) at an early stage of psychosexual development

fix-a-tion (fik'shən) n. [ME. *fixacion* < ML. *fixatio* < *fixatus*: see prec.] 1. a fixing, or fixating, or a being fixed, or fixated; specif., a) the directing and focusing of the eyes b) popularly, an exaggerated preoccupation; obsession 2. **Chem.** a) reduction into a solid or nonvolatile form b) the fixing of atmospheric nitrogen: see NITROGEN FIXATION 3. **Photog.** the treatment of a film, print, etc. to make it permanent 4. **Psychoanalysis** an arrest of the expression of the libidinal or aggressive drives at an early stage of psychosexual development, or a persistent attachment to some object or person that derives from this

fix-a-tive (fik'sat'iv) adj. [FIX + -ATIVE] that is able or tends to make permanent, prevent fading, etc. —n. a substance that makes something permanent, prevents fading, etc., as a mordant

fixed (fikst) adj. 1. firmly placed or attached; not movable

2. established; settled; set /a fixed price/ 3. steady; unmoving; resolute /a fixed purpose/ 4. remaining in the same position relative to the earth /a fixed satellite/ 5. persisting obstinately in the mind and tending to control the thoughts and action; obsessive /a fixed idea/ 6. **Chem.** a) nonvolatile; see FIXED OIL b) incorporated into a stable compound from its free state, as atmospheric nitrogen 7. [Colloq.] supplied with something needed, specif. money /comfortably fixed for life/ 8. [Slang] with the outcome dishonestly arranged beforehand /a fixed race/ —fix-ed-ly (fik'sid lē) adv. —fix'ed-ness n.

fixed charge any of certain charges, as taxes, rent, interest, etc., which must be paid, usually at regular intervals, without being changed and without reference to the amount of business done

fixed oil a nonvolatile oil, esp. one found in fatty animal tissue and the seeds of some plants

fixed star a star whose great distance from the earth makes it appear to keep the same position in relation to other stars

fix'er (fik'ser) n. 1. a person or thing that fixes 2. [Colloq.] a person who pays bribes or uses his influence to manipulate results, as in keeping others from being punished for illegal acts 3. [Slang] a person who sells narcotics illegally to addicts

fix-ings (-singz) n. pl. [*as* Colloq.] accessories or trimmings /roast turkey and all the fixings/

fix-i-ty (-sə tē) n. 1. the quality or state of being fixed; steadiness or permanence 2. pl. -ties anything fixed

fixt (fikst) poet, pt. and pp. of FIX

fix-ture (fiks'char) n. [*as* ME. *fixura* < L.

fjax: see FIX, alter in place 2. any of the etc. attached to the legally a part of it / thing that has remain seem fixed there 4 regularly occurring si fizz (fiz) n. [echoic] 1. effervescent drink 2. fizz'ing 1. to make a off gas bubbles; babbly 2. fizz'le (fiz'lē) vi. -zled silently, akin to listen a successful beginnin' sputtering sound 2 failure; fiasco

fizz-y (-ē) adj. fizz'ye

fjeld (fyeld) n. [Nor

plateau in Scandinav

fjord (fyôrd) n. same

Fl. 1. Flanders 2. F

fl. 1. floor 2. florin(s)

she) flourished 4. fl

Fla. Florida

flab (flab) n. [back-fo

flaccid flesh

flab-b-gast (flab'gəst)

AGHAST] to make s-

—SYN. see SURPRISE

flab-by (flab'ē) adj.

1. lacking firmness;]

2. lacking force; wea

fla-bel-late (fə bel'ə

shaped; also fla-bel'1

fla-bellum (-əm) n.

flabrum, a breeze < fl

1. a large fan carrie

monial occasions 2.

of the body

flac-cid (fak'sid) flas

1. hanging in loose fi

[flaccid muscles] 2

cid'ly n. —flac-cid

flack (flak) n. [*as*

[Slang] to serve as a

flack² (flak) n. same

fla-con (fla'kōn') E

flask with a stopper,

flag (flag) n. [LME

flutter] 1. a piece

staff, with distinctiv

used as a national o-

standard; ensign 2.

as on a hawk 3. th

certain dogs, as setts

cardboard, etc. atta

may be found easil

lines extending fro

note is an eighth, si

to decorate or mark

flag; esp., to signal t

message) by signali

dip the flag to salute

(or one's) flag 1. to

flag² (flag) n. [ME. /

base plāk, to spre

same as FLAGSTONE

flag (flag) n. [ME. /

wild irises with flat

blue, or yellow flow

2. same as SWEET F

or leaf of any of the

flag⁴ (flag) vi. flagge

fakken < ? ON. fl

strike 1. to become

weak or tired /of his e

***Flag Day** 1. June 1

the U.S. flag was ad

people give to some

flags in token of th

flag-el-lant (fla lə

flagellare: see FI

one who whips him

discipline or for s

flagellation

flag-el-late (fla lə

-lat'ing [*as* L. flage

< flagellum, a whip

beat, whence ON.

having a flagellum

like a flagellum —n.

flag-el-la-tion (fla

LL. (Ec.) flagellatio

fat, āpe, cār; ten, ēv

ē for a in ago, ē in ag

ū, Fr. duc; r, Fr. cr